U.S. Department of Justice

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Via Federal Express

Geoffrey Hobart, Esq.
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Washington, D.C. 20004

Re: Possible Civil Action Against McKesson Corporation for Violations of the Controlled Substances Act

Dear Mr. Hobart:

The United States Attorney's Office for the District of Colorado, in conjunction with the Drug Enforcement Administration ("DEA"), is investigating whether the McKesson Corporation's Aurora Distribution Center ("McKesson-Aurora"),[1] located at 14500 East 39th Avenue, Aurora, Colorado 80011, violated the Comprehensive Drug Abuse Prevention Control Act of 1970, 21 U.S.C. §§ 801 *et seq.*, ("CSA" or "Controlled Substances Act").

I. Introduction.

Colorado is grappling with an epidemic of prescription drug abuse and has the dubious distinction of having the second highest rate of prescription drug painkiller abuse in the United States. *See* Attachment 1, "State Estimates of Nonmedical Use of Prescription Pain Relievers," National Survey on Drug Use and Health (January 8, 2013). More than 255,000 Coloradans now misuse prescription drugs. *See* Attachment 2, "Colorado Plan to Reduce Prescription Drug Abuse," Office of Governor John Hickenlooper (September 2013), at 2. In recent years, prescriptions for certain

[1] Throughout this letter, "McKesson" will refer to McKesson Corporation, whereas "McKesson-Aurora" will refer to McKesson's distribution center located 14500 East 39th Avenue, Aurora, Colorado 80011.

prescription drugs like oxycodone have soared. *See* Attachment 3. And so have deaths due to use of these drugs. Deaths in Colorado related to opioid analgesics have quadrupled in recent years. *Id.* Recently, Colorado hospitals have also seen a dramatic increase in the numbers of babies born physically dependent upon drugs, including prescription drugs. *See* http://www.cpr.org/news/story/hooked-birth-6-percent-colorado-newborns-may-suffer-drug-withdrawal. The number of babies suffering from drug dependency at birth has doubled in the past five years at Children's Hospital Colorado located in Colorado Springs. *Id.* Similarly, Parkview Medical Center in Pueblo, Colorado reported 18 babies born dependent on drugs in 2013, up from only 2 babies in 2009. *Id.*

The DEA has a mandate to prevent illegal diversion of controlled substances. One of the important tools that the DEA relies on in accomplishing this task is suspicious-order reporting from DEA registrants. The CSA requires distributors like McKesson-Aurora to report suspicious orders to the DEA in order to assist the DEA with its law enforcement and regulatory efforts. *See* 21 C.F.R. § 1301.74(b).

This regulatory requirement to report to suspicious orders is not meaningless box-checking. Suspicious-order reporting serves a concrete, public-safety goal. Distributors are on the front lines and, thus, in a unique position to promptly advise the DEA when they receive an order that is unusual, deviates from a normal pattern, or is otherwise suspicious or inappropriate. If the distributor does not alert the DEA of such orders, then the DEA cannot take the necessary law enforcement steps to investigate the orders and prevent diversion. In this manner, distributors like McKesson-Aurora play a vital role in preventing diversion and saving lives.

Our investigation has determined that McKesson-Aurora failed to comply with its legal obligation to report suspicious orders. Although McKesson-Aurora paid lip service to a compliance program designed to prevent illegal diversion of controlled substances, this distribution center actually did very little to discover suspicious orders and report those orders to the DEA. Time and time again, McKesson-Aurora received information about orders that were unusual or exceeded even generous thresholds, but failed to report those orders. Many of the compliance controls in place to detect suspicious orders — such as site visits to pharmacies and pharmacy questionnaires — were either ignored or were treated by McKesson-Aurora personnel as perfunctory. McKesson-Aurora failed to take steps that could have potentially halted distribution to pharmacies of large amounts of controlled substances that were being dispensed for other than a legitimate medical purpose.

Our investigation has revealed that McKesson-Aurora repeatedly looked the other way, even when McKesson-Aurora was faced with very troubling evidence indicating potential diversion. It performed very little due diligence to determine why some of its independent pharmacy customers were ordering large quantities of controlled substances.

Even when McKesson-Aurora received information clearly showing suspicious orders by its pharmacy customers, it often failed to report even those obviously suspicious orders to the DEA. Instead, when McKesson-Aurora received a suspicious order from one of its pharmacy customers, the distribution center manipulated its internal control systems in various ways to avoid having to report that order.

The result was that readily identifiable orders and ordering patterns that were obvious signs of diversion occurring at McKesson-Aurora customer pharmacies went unreviewed and unreported. In this manner, McKesson-Aurora's desire for increased sales drove its compliance efforts.

McKesson-Aurora's failure to report suspicious orders to the DEA has had tangible and tragic consequences. At least nine overdose deaths in Colorado can be traced to purchases made at pharmacies that were purchasing unusually high quantities of oxycodone and hydrocodone from McKesson-Aurora. At least two drug-trafficking organizations were operating out of McKesson-Aurora-supplied pharmacies and diverting prescription drugs for sales on the street, but McKesson-Aurora never once reported those pharmacies' blatant pattern of suspicious ordering to the DEA.

II. Background on McKesson.

McKesson Corporation ("McKesson") is an industry leader in a profitable and growing pharmaceutical distribution market. It is the 15th largest company in the United States. It is one of three companies that control a combined 90% of the pharmaceutical distribution market in the United States. According to McKesson's securities filings, McKesson had a total of $122 billion in revenues ($105 billion of which is attributable to U.S. pharmaceutical distribution and related services) and $1.338 billion in profits in the 2013 Fiscal Year. These numbers have grown over time. In 2009, McKesson had a total of $106 billion in revenues ($96 billion of which was attributable to U.S. pharmaceutical distribution and related services) and $823 million in profits.

McKesson's distribution of controlled substances is a significant component of its overall business. McKesson owns and operates 28 facilities nationwide that are registered with DEA as distributors. These distribution centers service approximately 25,000 pharmacies daily and process 1.2 million order lines per night.

McKesson-Aurora is one of the 28 distribution centers and is registered with DEA as a distributor in controlled substances, Schedules II-V, pursuant to DEA Certificate of Registration PM0018425. McKesson-Aurora has approximately 530 customers. In 2011, McKesson-Aurora was recognized with the "Distribution Center of the Year" award.

III. McKesson-Aurora Had a Legal Obligation to Report Suspicious Orders to the DEA.

A. McKesson Is Required by the CSA to Report Suspicious Orders.

DEA registrants such as McKesson-Aurora are required to "maintain[] effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1). McKesson-Aurora is also required to "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b).

"Suspicious orders" is a broad phrase that includes, for example, "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *Id.* The DEA has also explained to registrants that these criteria are not all-inclusive, and that any of these factors render an order suspicious. *See* Attachment 4, Letter to Registrants from DEA Deputy Assistant Administrator Joseph Rannazzisi dated December 20, 2007 (explaining that these criteria are disjunctive and are not all inclusive). The DEA explained that, in practice:

- An order that deviates substantially from a normal pattern should be reported as suspicious, regardless of the size of the order. *Id.* at 1. The determination of whether an order deviates from the normal pattern depends not only on the ordering patterns of a particular pharmacy, but also on the registrant's entire customer base and relevant segment of the industry. *Id.* at 2.

- The size of an order, alone, can be enough to trigger the registrant's responsibility to report the order as suspicious. *Id.* at 1-2.

- It may not be enough for a registrant to establish a system that identifies an order as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage. *Id.* at 2. If the pharmacy placed unusually high orders from the beginning of its relationship with a distributor, this system would not detect those orders as suspicious. *Id.*

A registrant's responsibility does not merely stop with the reporting of the suspicious order to the DEA. In addition, "[r]egistrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels." *Id.* at 1. That means that registrants that routinely fill these orders — without first determining whether the order is likely to be diverted — are failing to maintain effective controls against diversion.

B. McKesson-Aurora Undertook Additional Obligations in the 2008 Settlement Agreement and the 2008 Memorandum of Agreement.

In 2008, McKesson entered into a Settlement Agreement with the Department of Justice and a Memorandum of Agreement ("MOA") with the DEA related to, among other things, McKesson's failure to report suspicious orders of controlled substances to the DEA, as required by 21 C.F.R. § 1301.74(b). The settlement involved CSA violations by McKesson from multiple districts around the country, including the District of Colorado. The Colorado violations resolved by the settlement related to McKesson-Aurora's failure to report the purchases of large quantities of hydrocodone by three Colorado pharmacies: Brighton Pharmacy in Brighton; Western States Pharmacy in Brighton; and St. Vrain's Pharmacy in Lyons. *See* Attachment 5, Settlement Agreement, at ¶ 8D. Under the terms of the April 30, 2008 Settlement Agreement, McKesson agreed to pay the United States $13,250,000 in exchange for a release from civil liability under 21 U.S.C. § 842(c)(1). *See id.* at ¶¶ 13-14.

On May 2, 2008, McKesson also entered into the MOA with the DEA. *See* Attachment 6, Memorandum of Agreement. McKesson-Aurora was specifically mentioned in Appendix A of the MOA. Under the terms of the MOA, McKesson agreed to comply with its obligations under federal law in the future:

- McKesson agreed to maintain a compliance program designed to detect and prevent diversion, including a program to review orders for controlled substances. *Id.* at ¶ II.1.a.

- McKesson agreed that if a controlled substance order exceeded "established thresholds and criteria," those orders would be reviewed by a McKesson employee "trained to detect suspicious orders." *Id.*

- McKesson agreed that if it discovered a suspicious order, it would report the order directly to DEA Headquarters (rather than the local DEA field office, as required by the federal regulations). *Id.* at ¶ II.1.c.

In sum, after the MOA, McKesson-Aurora had a regulatory obligation under 21 C.F.R. § 1301.74(b) stemming from its status as a DEA registrant, as well as a contractual obligation stemming from the 2008 Settlement Agreement and MOA, to report suspicious orders of controlled substances to the DEA. McKesson-Aurora — of all drug distributors registered as DEA registrants — should have been particularly attuned to its obligation to report suspicious orders.

IV. McKesson Further Agreed to a Controlled Substance Monitoring Program.

A. The CSMP Recognizes McKesson's Duty to Detect Suspicious Orders.

As a direct result of the 2008 settlement, McKesson developed a program called the Controlled Substance Monitoring Program ("CSMP"), in which McKesson recognizes that it has a duty to monitor its sales of all controlled substances so that it can report suspicious orders to the DEA. According to McKesson's Operations Manual, the purpose of its CSMP is to

- "Proactively review the customer's order and purchases for all controlled substances in order to detect and prevent diversion
- Set and maintain customers' thresholds for all controlled substances
- Make informed decisions based upon established threshold information
- Build a documented business case to substantiate the volume of controlled substances purchased by McKesson customers
- Report to the DEA those orders / purchases / customers designated as 'suspicious'."

See Attachment 7, CSMP Operations Manual dated September 16, 2008.[2]

B. The CSMP was Intended to Set, and Maintain, Thresholds.

As noted, the CSMP explains that one of its purposes is to "[s]et and maintain customers' thresholds." These thresholds are the maximum dosage units of a particular drug (assigned a "base code" by the DEA) that each customer is allowed to purchase from McKesson in any given month. In other words, one of the stated goals of the CSMP is to set the maximum monthly amount of a given controlled substance that a pharmacy customer can purchase, and then use that threshold to detect diversion by monitoring when the customer exceeds the threshold.

Under the CSMP, once a customer reaches its monthly maximum threshold amount, McKesson is supposed to "block" all subsequent orders for that item for the remainder of the month. The following month, the customer's sales history is "refreshed" and the sales for that item are set back to zero, allowing the customer to once again purchase up to the threshold amount.

[2] For the purposes of this letter, the description of the CSMP refers to its application to independent retail pharmacies.

At the outset, McKesson is supposed to establish thresholds based upon each individual pharmacy's past ordering patterns. For existing customers, McKesson "originally set up the thresholds in 2008 based on an existing customer's 12 month usage number on a particular basecode" by "[taking] the highest month of that year and add[ing] 10%" — a "buffer [that] allowed for unusual fluctuations from month to month." *See* Attachment 8, MCK_00165197. For new customers, the CSMP requires McKesson to establish thresholds by having the new customer complete a questionnaire and provide three months of sales history. *See* Attachment 7, at Section 1.2.2. McKesson relies on a "Family Matrix" that it created to establish minimum thresholds for each drug code based upon the customer type (retail national account, hospital, independent retail pharmacy, etc.) and purchasing volume. Once the customer type and purchasing volume are determined from the customer questionnaire, McKesson is supposed to apply the Family Matrix to establish initial thresholds for new customers.

The CSMP also sets forth the method by which a customer's threshold for a particular drug code can be increased. *Id.* at Section 1.3. A McKesson representative, typically sales personnel, will complete a threshold change request ("TCR") form, justifying why the pharmacy needs to increase the threshold for a given month. The TCR form documents why the pharmacy needs an increase (*i.e.*, increase in business, emergency request, etc.). Threshold increases can be temporary for that month or permanent. Threshold changes must be approved by the Regional Director of Regulatory Affairs ("DRA"). For McKesson-Aurora, the Regional DRA is Tom McDonald.

C. Warning Reports and Omit Reports.

The CSMP states that McKesson is to provide customers with two reports as customers approach their monthly threshold for a particular drug: a "warning report" as the customer approaches the threshold, and an "omit report" if the threshold is reached.

A threshold "warning report" is supposed to issue when a pharmacy customer reaches 90 percent of its threshold for a particular drug. The DRA is supposed to notify the McKesson-Aurora distribution center management that the customer is at 90 percent. *Id.* at Section 2.1. The distribution center management can then contact the customer and discuss increasing threshold levels, at their discretion. An invoice is also supposed to be generated to alert the customer that it has reached 90 percent of its threshold.

A threshold "omit report" — sometimes referred to as a threshold "incursion report"[3] — is issued once a pharmacy customer reaches its monthly maximum threshold amount. At that point, all subsequent orders for that item are supposed to be blocked. *Id.*

[3] In at least one instance, the CSMP refers to this as "Threshold Excursion" rather than "Threshold Incursion." *See* Attachment 7, at Section 2.2.

at Section 2.2. The only way for a customer's order to become "unblocked" is if (1) the threshold is temporarily changed, (2) the threshold is permanently changed, (3) the customer returns some product such that the customer falls below the threshold, or (4) the sales history becomes refreshed at the beginning of a new month. *Id.*

D. The CSMP Recognizes McKesson's Duty to "Know Their Customer."

The CSMP dictates that all McKesson distribution centers, including McKesson-Aurora, must "know their customer." *Id.* at 1. According to the CSMP, "[t]his means understanding the customer's business, *why* they purchase as well as how much they purchase. Factors such as type of business, internet activities, type and quantity of products purchased should be considered when evaluating a customer." *Id.* (emphasis in original). The CSMP sets forth several ways in which McKesson can garner an understanding of its customers' businesses:

- Pharmacy Questionnaires: The CSMP requires the completion of detailed Pharmacy Questionnaires for new and existing customers, on a periodic basis. *Id.* at Section 3.2.

- Site Visits: The CSMP also states that McKesson is to conduct physical site visits to its customers' stores. On these site visits, McKesson personnel are to observe, among other things, whether the "customer's business [is] in a site that appears consistent with their business type and volume?" The CSMP expressly states that personnel should consider the population and other businesses located in the surrounding area. *Id.* at Section 3.2.2.7.

- Customer Interviews: McKesson's CSMP also has a separate provision for a "Customer Interview." The interview is supposed to occur at the pharmacy site in order to "view the pharmacy operations." Further, the interview is supposed to be scheduled as soon as possible because "DEA expects McKesson's responses to suspicious activities to be prompt and timely." *Id.* at Section 3.3.

The CSMP notes that McKesson can also conduct further "due diligence" through an inquiry with the DEA or the Board of Pharmacy, an internet search, or extensive background search via corporate security.

E. The CSMP Requires Higher-Level Review of Potentially Suspicious Orders.

The CSMP provides a system for higher-level management review of potentially suspicious orders. If a customer reaches its threshold and receives an omit report for a

particular controlled substance, the review may involve local, regional, or national management:

- Level 1 Review: A Level 1 review is ***required*** for all threshold incursions. McKesson's local distribution center management is supposed to contact the customer upon the incursion and advise the customer that a controlled substance has been omitted because the threshold has been met. Management will then undertake to determine why the incursion has occurred, inquiring as to whether the customer has any new business and possibly evaluating the customer's last three months of purchases. Local distribution center management can request a temporary or permanent threshold change, but if the evaluation of the order is inconclusive, then McKesson is supposed to escalate the matter to a Level 2 review. *Id.* at Section 2.2.2.

- Level 2 Review: The local distribution center management can forward all information from the Level 1 review to the Regional DRA. The DRA will then discuss the review process with the distribution center management and determine if the sales were appropriate. There are three possible outcomes from a Level 2 review: (1) McKesson can continue to block the controlled substance until the following month when the sales history is refreshed, (2) McKesson can request a temporary or permanent threshold change, or (3) the DRA can escalate the matter to a Level 3 review. *Id.* at Section 2.2.3.

- Level 3 Review: If the Level 1 and Level 2 reviews conclude that the order is potentially suspicious, a Level 3 review is supposed to be conducted by senior national McKesson management. At this point, ***all*** controlled substance sales to that customer are supposed to be blocked. McKesson is then supposed to report the customer and transaction to DEA headquarters as "suspicious." *Id.* at Section 2.2.4.

The CSMP further mandates that McKesson take action if it thinks that a customer is engaging in inappropriate activity or questionable practices, even if the order amounts did not reach any thresholds. According to the CSMP Operations Manual, "[i]f at any time McKesson (this includes sales, operations, regulatory) suspects any wrong doing, inappropriate activity and/or questionable practices, McKesson has the responsibility to react. This requirement is regardless of customer type, size, tenure, revenue, purchase quantities or threshold amounts." *Id.* at Section 4. The CSMP also gives the regulatory department the ability to block a controlled substance to a customer or suspend a shipment of controlled substances to any customer at any time. *Id.* at Sections 2.3 and 4.

V. McKesson-Aurora's Failure to Report Suspicious Orders to the DEA.

A. Between 2008 and 2013, McKesson-Aurora Submitted Only 16 Suspicious Order Reports.

After specifically agreeing to come into compliance with 21 C.F.R. § 1301.74(b) under the terms of the 2008 MOA, McKesson-Aurora submitted almost no suspicious order reports ("SORs") to the DEA from 2008 through 2013, as set forth below:

- From May 2, 2008, through March 25, 2012, McKesson-Aurora did not submit any SORs to the DEA.

- On March 26, 2012, McKesson-Aurora submitted 16 SORs to DEA Headquarters. All 16 SORs were submitted in a single batch and they all related to one pharmacy: Dales's Pharmacy in Fort Lupton, Colorado, DEA No. FD1023097. All 16 SORs were for orders that had been placed between January 20, 2012, and March 13, 2012, with no explanation for the untimely delay in submitting some of these reports to the DEA.

- From March 27, 2012, through June 23, 2013, McKesson-Aurora did not submit any SORs to the DEA.

- On March 12, 2013, the United States executed its Administrative Inspection Warrant and simultaneously served McKesson-Aurora with a subpoena for documents.

- From June 24, 2013, through November 30, 2013, McKesson-Aurora submitted approximately 2,447 SORs to the DEA.

Thus, in the five years before McKesson-Aurora knew that it was being investigated but was subject to the MOA, it reported a total of 16 orders as suspicious, in one batch, occurring in one quarter, at one pharmacy that McKesson-Aurora had recently terminated. To put that figure in its proper perspective, McKesson reported to the DEA ARCOS system that it received, processed, and filled a total of 1.6 million orders for controlled substances during that same time frame. This disparity, alone, demonstrates that McKesson Aurora was operating for years without any functional "system to disclose . . . suspicious orders of controlled substances" to be reported to the DEA. *See* 21 CFR 1301.74(b).

It was not until after the United States served a warrant and subpoena — and made it known that the United States was actively investigating whether McKesson-Aurora had complied with its regulatory and MOA obligations to report suspicious orders — that McKesson-Aurora suddenly began reporting suspicious orders to the DEA. This

very act of reporting almost 2,500 SORs in a five-month period in 2013 is strong evidence that McKesson-Aurora knew it should have been reporting suspicious orders all along.

B. McKesson-Aurora's Desire for Increased Sales Overrode Its Obligations to Report Suspicious Orders.

Our investigation has revealed a disturbing pattern: McKesson-Aurora's desire for increased sales and retaining its customers overrode its obligations to report suspicious orders. We have identified this trend across several different areas.

1. *McKesson-Aurora Manipulated and Circumvented Thresholds.*

Thresholds were supposed to be the linchpin of McKesson's compliance program. But McKesson-Aurora manipulated customers' threshold levels, in numerous ways, to avoid rigorous internal review.

First, McKesson-Aurora set its initial thresholds for its pharmacy customers very high. McKesson-Aurora's review process was not even triggered until an individual pharmacy sold more than 10% of that pharmacy's average volume from a 12-month period from 2007-2008 — a year in which McKesson had settled claims because diversion was flourishing in McKesson-supplied pharmacies.

Moreover, McKesson's CSMP did not even attempt to detect if diversion was already occurring back in 2008 when the initial thresholds were set. Thus, to the extent diversion was already occurring, such diversion could continue, as long as the customer did not stray too far from those initial thresholds.

In some cases, McKesson-Aurora set some thresholds so high at the outset that the pharmacy customer would never exceed it, and thus, never trigger any review as to whether an order was indeed suspicious. This appears to have happened with hydrocodone purchases more than oxycodone purchases. Take, for example, PDC Pharmacy Inc. dba Goose Creek Pharmacy. Our analysis indicates that McKesson-Aurora set Goose Creek's hydrocodone monthly threshold at 8,000 dosage units, which was about 5,000 dosage units higher than Goose Creek's typical ordering pattern of 1,000 to 3,000 dosage units. *See* Attachment 9, PDC Pharmacy (hydrocodone). In another example, on June 10, 2009, the owner of the Lajara Pharmaceutical Center reported that he sold 6,500 dosage units of hydrocodone products per month. Yet McKesson-Aurora set Lajara Pharmaceutical Center's hydrocodone threshold at 13,000 dosage units a month — double the amount that this pharmacy estimated it would be purchasing. By setting the hydrocodone thresholds well above the pharmacy's typical monthly ordering quantity, McKesson-Aurora avoided its obligation to keep an eye on whether sales to these pharmacies were in fact deviating from the normal pattern.

Second, McKesson-Aurora routinely manipulated the thresholds. It would often preemptively increase the thresholds of its customers on particular drugs before the customers had even submitted a TCR seeking a threshold increase. These preemptive threshold increases were often in response to either the threshold warning reports or omit reports — the very reports that McKesson was supposed to rely upon to "investigate customer activity." For instance:

- In an email dated February 28, 2012, Jake Kramer, Distribution Center Manager for McKesson-Aurora, emailed Robert Perrich, Operations Manager at McKesson-Aurora, and asked the following question: "Can you call Prescription Shop and see if they need an adjustment? He wasn't in when I called today and should be there by now . . . ." *See* Attachment 10, Bates No. MCK_00030152.

- In email dated December 27, 2012, Perrich sent an email to Beau Bradley, Inventory Manager, and asked: "REDACTED is now on here for Hydrocodone…also we have REDACTED. Do you think we should do ***pre-emptive*** TCR for these two?" *See* Attachment 11, Bates No. MCK_00010740 (emphasis added).

Time and time again, McKesson-Aurora increased a customer's threshold in a particular month so that the customer did not exceed that threshold and thus trigger McKesson-Aurora's obligation to conduct a Level 2 or Level 3 review (much less file a SOR with the DEA). McKesson-Aurora simply kept raising the threshold bar so that it accommodated the customer's ordering pattern without triggering review or restricting any customer's access to as much controlled substances as it wanted to purchase. We have attached charts for several pharmacies that demonstrate this pattern. *See* Attachment 12, Blende Pharmacy (hydrocodone), Dale's Pharmacy (oxycodone), Beattie's (oxycodone), Todd's Pharmacy (oxycodone).

Third, McKesson-Aurora was often willing to increase a pharmacy's threshold for the flimsiest of reasons and without adequate investigation. To give just a few of many examples:

- Dale's Pharmacy requested an increase of its oxycodone threshold on December 27, 2010. Dale's proffered justification for the TCR was "[n]ormal business with increased volume during the holidays." *See* Attachment 13, Bates No. MCK_000168027. Although there were only four days remaining in the month until Dale's oxycodone would be reset, McKesson-Aurora approved an 8,000 dosage unit increase of Dale's oxycodone threshold, increasing the threshold by 20.5 percent from 39,000 to 47,000 dosage units.

- From June 2010 through November 2010, McKesson-Aurora justified multiple threshold increases for Dale's Pharmacy based upon an alleged "influx of customers" due to the closure of a neighboring pharmacy in Fort Lupton. Several of the TCR's for Dale's justified requests for threshold increases on the grounds that the "API Pharmacy" had stopped selling controlled substances. In point of fact, the API Pharmacy had closed seven years earlier in 2003. The Pharmacy at Salud, another pharmacy in Fort Lupton, did stop selling controlled substances for 19 days in June 2010. However, McKesson-Aurora allowed Dale's to rely on this closure excuse for continued threshold increases for another four months, even after the Pharmacy at Salud was back up and running. *See* Attachment 14, Bates No. MCK_168019-168020; MCK_169024-168025.

- McKesson-Aurora justified a 7,000-dosage unit increase of oxycodone to Beattie's Pharmacy in Brighton on the grounds that the pharmacy had been robbed. On July 9, 2009, Beattie's was robbed of 2,448 dosage units of oxycodone. In response, Beattie's requested a threshold increase of 6,000 dosage units. Rather than simply raising the threshold to allow for the replacement of the 2,448 pills that had been stolen, McKesson-Aurora authorized a ***7,000*** dosage unit increase to Beattie's oxycodone threshold — 1,000 dosage units more than the pharmacy even requested and 4,500 dosage units more than was warranted by the robbery it used to justify the request.

Fourth, our review of McKesson-Aurora's due diligence files reveals that McKesson-Aurora frequently failed to provide justifications as to why a customer's threshold was being increased. This directly contradicted the CSMP, which requires searching review and emphasizes the duty to know the customer. *See* Attachment 7.

In sum, thresholds that were originally intended to trigger an investigation that could result in a suspicious order being reported to the DEA never served this purpose. McKesson did not "set" and then "maintain" its thresholds, as required by its CSMP. The thresholds did not meaningfully restrict McKesson-Aurora's customers from obtaining controlled substances. Thresholds were moved to accommodate whatever purchasing occurred, or they were set so high that they never triggered any review. In fact, as explained below in Section V.C.1, *infra*, we even have evidence that thresholds were frequently exceeded without consequence, given that McKesson-Aurora neither meaningfully investigated the threshold incursion nor submitted any suspicious order reports to the DEA.

2. *McKesson-Aurora Did Not Actually Use the Three-Level Review Process to Carefully Review Potentially Suspicious Orders.*

The CSMP set up the Level Review process described in Section IV.E, *supra*. However, our investigation found no evidence that McKesson-Aurora ever conducted a Level 2 or Level 3 review for ***any*** of its pharmacy customers between 2008 and 2013.

Although McKesson-Aurora did, from time to time, conduct Level 1 reviews, it often did not take adequate time to conduct a ***meaningful*** Level 1 review focused on detecting suspicious orders. For example, on approximately six separate occasions, McKesson-Aurora completed an omit report, Level 1 review, and TCR for Blende Drug, all on the same date. Likewise, on seven separate occasions, McKesson completed an omit report, Level 1 review, and TCR for JB Pharmacy, all on the same date. Performing the review on the same day that the threshold change was approved indicates that McKesson-Aurora's review of the proffered justification for the threshold change was cursory, and that the company was not interested in digging too deeply to determine if the justification was valid.

Under the CSMP, the omit report was supposed to trigger an investigation into whether an order was suspicious. But in practice McKesson-Aurora ignored the CSMP. Instead of looking at omitted orders to see if those orders were suspicious, McKesson-Aurora looked at omit reports to see if the customers needed a threshold increase. *See* Attachment 10. Essentially, the omit report became a sales tool, rather than a way of monitoring orders to try to detect and prevent diversion. And on those occasions when a pharmacy said that it did not need a threshold increase, McKesson-Aurora did nothing further to investigate whether the threshold incursion involved a suspicious order and, following an investigation, report that order as suspicious.

3. *McKesson-Aurora Failed to Conduct Adequate Due Diligence.*

McKesson-Aurora also failed to conduct due diligence, even when faced with possible diversion. Take, for example, the manner in which McKesson-Aurora conducted due diligence on JB Pharmacy, one of its independent pharmacy customers located in Pueblo, Colorado. In answering the question on a Pharmacy Questionnaire about the monthly dosage units dispensed for hydrocodone and oxycodone, JB Pharmacy reported 15,100 and 17,500 dosage units, respectively. To explain why its numbers were greater than 5,000 dosage units, JB Pharmacy stated that "Overusage by neurologists + other prescribers." *See* Attachment 15, Bates No. MCK_000413-000420. This "Overusage" comment prompted an email exchange between Tom McDonald, McKesson's DRA for the Western Region, and Jake Kramer, McKesson-Aurora's Distribution Manager. *Id.* McDonald questioned Kramer as to JB Pharmacy's stated explanation, and Kramer justified continuing to do business with JB Pharmacy in part

because "[t]his is a long time and very influential independent, basically what he says[,] so goes our entire independent customer base." *Id.* McDonald then approved the TCR. *Id.* The fact that this particular pharmacy was a "very influential" customer should have had no weight in McKesson-Aurora's determination about whether it was filling suspicious orders and whether McKesson-Aurora should accommodate (by raising its threshold) the "overusage" of controlled substances that this pharmacy was reporting.

Although the CSMP discussed the possibility of conducting site visits so that McKesson-Aurora could better understand their customers' business, these visits appear to have been largely perfunctory and well recognized as such. For instance, on August 19, 2010, Jake Kramer sent an email to John Schultz, a sales manager handling customers located in southern Colorado, with a list of customers that Kramer wanted to visit. Kramer asked Schultz to set up the site visits. In this email, Kramer stated "Below is a list of 'must-see' accounts. Their monthly thresholds are at a level [sic] I would like to visit them again and see the business for myself. They have 'absolutely' nothing to worry about but part of the CSMP requirement is that I visit accounts over a certain threshold." *See* Attachment 16, Bates No. MCK_00168442-00168444.

McKesson-Aurora also failed to conduct due diligence when it came to analyzing a customer's ratios of controlled substances to non-controlled substances, and ratios of oxycodone to other controlled substances. Analyzing these ratios is one way to determine whether diversion might be occurring at a pharmacy; after all, if a pharmacy customer was purchasing all of its drugs exclusively from McKesson, and 90 percent of its purchases were controlled substances and only 10 percent were non-controlled substances, that might be a warning to McKesson that it should investigate the pharmacy's transactions to ensure its sales were not resulting in diversion. At one point, Tom McDonald had provided Jake Kramer with data showing a McKesson-Aurora customer with a high ratio of oxycodone to non-controlled substances. This, apparently, did not trigger any alarm for McKesson-Aurora because high ratios were the rule rather than the exception. On September 26, 2012, Jake Kramer wrote an email to Tom McDonald in which he stated, "Everybody is high Tom; are we suppose [sic] to cut everyone off?" *See* Attachment 17, Bates Nos. MCK_00167825–00167827.

4. *McKesson-Aurora Failed to Provide Its Sales Representatives With Adequate Guidance on How to Implement the CSMP.*

As part of our investigation, we have interviewed several former sales representatives. These sales reps have all consistently explained that the personnel in the distribution center's warehouse were responsible for monitoring orders to determine if any particular order was suspicious. While a great deal of effort went into getting sales reps to increase sales, little or no effort was spent on training these sales reps to ensure compliance with the CSA.

The CSMP provides little to no guidance to the sales reps or the distribution center management regarding the identification of potentially suspicious orders. Our investigation revealed that the CSMP was nothing more than a "how to" guide for filling out CSMP paperwork, rather than a tool by which McKesson employees could evaluate potentially suspicious orders.

Additionally, our investigation revealed that McKesson had a separate CSMP Standard Operating Procedure ("SOP") for its Service First employees, who are the McKesson sales personnel responsible, in part, for implementing the CSMP. Nowhere in the 14-page document does McKesson give guidance as to how to detect a suspicious order. *See* Attachment 18. Instead, the SOP directs Service First representatives to preemptively ask customers for a threshold change whenever a customer approaches its monthly threshold. Accordingly, the separate CSMP SOP directed these Service First representatives to bypass the thresholds, rather than hold customers to those thresholds or figure out why the customers had reached the thresholds.

5. *McKesson-Aurora Gave Its Employees Guidance on How to Avoid Creating Adverse Evidence.*

The CSMP Operations Manual contains a troubling directive to McKesson employees to communicate in a manner that will not require the company to report suspicious orders to the DEA. The Operations Manual directs McKesson employees to "[w]rite information as if it were being viewed by the DEA," and it specifically instructs employees to "refrain from using the word 'suspicious' in communications" describing customer orders. *See* Attachment 7, at Section 4. As the Manual explains, "Once McKesson deems an order and/or customer suspicious, McKesson is required to act. This means all controlled substance sales to that customer must cease and the DEA must be notified." *Id.* Language such as this confirms that McKesson understood that it has an obligation to report suspicious orders, but that it consciously took steps to avoid having to report.

C. Many Suspicious Orders Went Unreported.

Following the execution of the Administrative Inspection Warrant and the subpoena in March 2013, the United States has focused on 15 of McKesson-Aurora's pharmacy customers. The pharmacies comprising this sample were selected on a variety of criteria, including McKesson-Aurora's own representations about its Top 50 largest purchasers of oxycodone and hydrocodone.

Our analysis of this small sample of McKesson-Aurora's 530 customers shows that there were many orders that McKesson-Aurora should have reported to the DEA as suspicious, under the definition set forth at 21 C.F.R. § 1301.74(b) and the Rannazzisi letter dated December 20, 2007 (Attachment 4). However, not only did McKesson-

Aurora not report ***any*** of these orders to the DEA, McKesson-Aurora's due diligence files show that the company did nothing to investigate whether these orders were suspicious.

1. *McKesson-Aurora Failed to Report Orders That Exceeded the Threshold.*

The CSMP Operations Manual states that McKesson distribution centers are not to fill orders that exceed a customer's threshold for a particular drug. However, our analysis shows that McKesson-Aurora routinely broke this rule. We have uncovered numerous examples of McKesson-Aurora's pharmacy customers ordering more dosage units than their established thresholds, and McKesson-Aurora filling those orders without reporting them to the DEA as suspicious. For example:

- Lajara Pharmaceutical Center in La Jara, Colorado exceeded its monthly threshold for oxycodone purchases in March 2010, January 2012, and March 2012. *See* Attachment 19, Lajara Pharmaceutical Center (oxycodone).

- Todd's Harvard Park Pharmacy in Denver exceeded its monthly oxycodone thresholds on eight separate occasions: March 2010, August 2010, May 2011, November 2011, February 2012, July 2012, August 2012, and May 2013. *See* Attachment 12.

- We have seen examples of pharmacies exceeding their thresholds by hundreds and thousands of dosage units. For instance, Valley Wide Pharmacy in Alamosa, Colorado exceeded its oxycodone threshold by 2,000 dosage units in September 2011 and 1,500 dosage units in February 2012. *See* Attachment 20, Valley Wide Pharmacy (oxycodone).

The due diligence files for Lajara Pharmaceutical Center, Todd's Harvard Park Pharmacy, and Valley Wide Pharmacy provide no explanation as to why McKesson-Aurora allowed the pharmacies to breach their thresholds. Nor do the files give any indication that McKesson-Aurora did anything to investigate whether these or other orders were suspicious. No suspicious orders were reported to the DEA for these pharmacies for any of these months.

2. *McKesson-Aurora Failed to Report Orders of Unusual Size.*

Under 21 C.F.R. § 1301.74(b), suspicious orders are defined to include "orders of unusual size." Our investigation has demonstrated that McKesson-Aurora filled many orders of unusual size that it did not report to the DEA, including:

- In November 2011, Chase Pharmacy in Byers, Colorado placed and McKesson-Aurora filled orders for 26,000 dosage units of oxycodone. This amount was more than double the 10,400 dosage units of oxycodone that Chase had ordered in October 2011, and 5,000 dosage units more than the 21,000 dosage units Chase had ordered in September 2011. *See* Attachment 21, Chase Pharmacy (oxycodone).

- Valley Wide ordered 4,900 dosage units of oxycodone in August 2011. In September 2011, Valley Wide ordered 12,000 dosage units. This amount was 3,500 dosage units larger than Valley Wide's highest prior order of 8,500 dosage units in March 2011. *See* Attachment 20.

- Alamosa Pharmacy in Alamosa, Colorado ordered 2,300 dosage units of hydrocodone in February 2010. The following month, the pharmacy more than doubled its purchases, ordering 5,400 dosage units of hydrocodone. *See* Attachment 22, Alamosa Pharmacy (hydrocodone).

- Blende Pharmacy in Pueblo, Colorado almost quadrupled its order of hydrocodone without raising a red flag at McKesson-Aurora. Blende ordered 4,100 dosage units in June 2012, and 16,300 dosage units in July 2012. *See* Attachment 12.

The geographic locations and surrounding populations of certain pharmacy customers should have indicated to McKesson-Aurora that the size of their controlled substance orders were suspicious. For instance:

- La Jara, Colorado is located in a very rural area of the state. The town has a population of 818 people, of whom 80% (654 people) are adults, according to the 2010 U.S. Census. Yet the Lajara Pharmaceutical Center was routinely among McKesson-Aurora's top purchasers for various controlled substances alongside pharmacies servicing much more densely populated areas, purchasing 240,100 dosage units of oxycodone and 110,460 dosage units of hydrocodone in 2012. It was highly suspicious that this pharmacy was ordering controlled substances in amounts that were disproportionate to the population it served.

- Chase Pharmacy is located in Byers, Colorado, which has a population of 1,160, 74% of whom were adults, according to the 2010 U.S. Census. In 2012, Chase purchased 171,700 dosage units of oxycodone and 107,600 dosage units of hydrocodone from McKesson-Aurora, amounting to 200 dosage units of oxycodone and 125 dosage units of hydrocodone for every adult in Byers in 2012.

Despite McKesson-Aurora's "know your customer" directive, it is clear that McKesson-Aurora did not even use plain common sense when it came to scrutinizing its customers' purchases, let alone engage in meaningful attempts to know its customers. Compare the total purchases made by Dale's Pharmacy, which is located in Fort Lupton, to another McKesson-Aurora customer, Safeway, which is located just down the road in Fort Lupton. Dale's was ordering anywhere from seven to 12 times as much oxycodone, and about three times as much hydrocodone, as the Fort Lupton Safeway between 2009 and 2011. *See* Attachment 23, Dale's v. Safeway Yearly Sales. These sales numbers are unusual, given that independently owned pharmacies like Dale's do not typically out-order national chain pharmacies like Safeway. Despite these numbers, McKesson-Aurora did not file any suspicious order reports on Dale's with the DEA until March 2012.

3. *McKesson-Aurora Failed to Report Orders of Unusual Frequency.*

McKesson-Aurora also failed to report orders of unusual frequency to the DEA, in violation of 21 C.F.R. § 1301.74(b). For instance, our analysis shows that Blende Pharmacy typically submitted to McKesson-Aurora anywhere from one to five orders of hydrocodone each day. *See* Attachment 24, Blende Pharmacy (hydrocodone frequency chart). On November 23, 2010, Blende placed 14 orders of hydrocodone in a single day. *Id.* Likewise, on March 20, 2012, Blende placed 25 orders of hydrocodone — over five times more than Blende's typical number of orders — in a single day. *Id.* McKesson-Aurora reported none of this conduct to the DEA as suspicious.

VI. McKesson-Aurora's Failure to Identify and Report Suspicious Orders Caused Significant Public Harm.

This is not a CSA investigation where the harm to the public is merely theoretical. McKesson-Aurora's calculated business decision not to report suspicious orders had tragic and severe consequences.

Thus far, our investigation has identified at least nine individuals who died of a drug overdose from prescription drugs purchased from several different pharmacies that had purchased those controlled substances from McKesson-Aurora.

In addition, the DEA uncovered a dangerous drug-trafficking organization ("DTO") operated by Robin Steinke in and around Denver that relied upon the Platte Valley Family Pharmacy in Brighton for its supply of illegally obtained controlled substances. Jeffrey Clawson, the owner of the pharmacy and a DEA registrant, voluntarily spoke with DEA investigators and admitted that he was involved in filling fraudulent prescriptions for Steinke and individuals associated with Steinke. Clawson admitted that this conduct occurred from April 2010 through May 2012, when he voluntarily surrendered his DEA registration. During this same time period, McKesson-Aurora was the sole supplier of drugs to Platte Valley Family Pharmacy.

McKesson-Aurora should have been paying especially close attention to Clawson and the purchases made by the Platte Valley Family Pharmacy between 2008 and 2012. That is because Clawson is the former pharmacy manager of the Brighton Family Pharmacy, which is one of the three pharmacies that were the subject of the Colorado covered conduct in the 2008 Settlement Agreement. However, despite vast increases in the amounts of controlled substances (particularly oxycodone) ordered by Platte Valley Family Pharmacy, McKesson-Aurora never reported ***any*** suspicious activity to the DEA during the time that the pharmacy was serving as a source of supply of controlled substances for the DTO.

A Colorado state grand jury subsequently indicted Clawson, Steinke, and 13 others for Racketeering, Conspiracy to Distribute Controlled Substances, and Distribution of Controlled Substances. *See* Attachment 25, Indictment. Significantly, McKesson was also mentioned in the indictment:

> A key issue during this time period was that McKesson, like all other DEA registered suppliers, had an obligation under the federal Controlled Substances Act, to report to DEA suspicious sales or orders of controlled substances. The Grand Jury learned of evidence demonstrating that Clawson's Platte Valley Pharmacy engaged in the regular purchase of Oxycodone from McKesson that was either unusually large, unusually frequent, and/or which substantially deviated from the normal pattern typically observed for comparable pharmacies in the area in and around Brighton, Colorado. From 2008-2011 the percentage increase for Oxycodone 30mg orders supplied by McKesson to Platte Valley Pharmacy was approximately 1,469%. Further, evidence was presented that the DEA did not receive any reports from McKesson regarding Platte Valley Pharmacy's purchase of Oxycodone that were arguably suspicious in terms of quantities and frequency.

Id. at 12.

McKesson-Aurora's due diligence file for Platte Valley Family Pharmacy provides countless indications of suspicious ordering patterns, all of which were ignored by McKesson-Aurora personnel. In addition, though McKesson was aware that Clawson had previously served as the pharmacy manager at Brighton Family Pharmacy, which was one of the Colorado pharmacies involved in the 2008 Settlement Agreement, this fact

did not raise any red flags regarding the large amounts of oxycodone being ordered by Clawson at Platte Valley Family Pharmacy.[4]

VII. Penalty.

As a DEA registrant, McKesson-Aurora is required by the CSA to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and to "inform" the DEA of those suspicious orders when discovered. 21 C.F.R. § 1301.74(b). Any such "refus[al] or negligent[] fail[ure] to make, keep, or furnish any . . . report . . . or information required" by the CSA is a violation of federal law and punishable by a civil penalty of up to $10,000. 21 U.S.C. §§ 842(a)(5) and (c)(1)(B). Such punishment is intended to impress upon registrants the importance of their role in maintaining effective controls against diversion.

McKesson's payment of $13,250,000 in 2008 for failing to file suspicious order reports did little to impress upon the company the concrete, public-safety consequences of its failure to obey the law. Given that, and applying the penalty factors set forth above, we will seek at trial the maximum civil penalty permissible for each instance in which McKesson-Aurora failed to inform the DEA of a suspicious order.[5]

VIII. Conclusion.

McKesson-Aurora made a calculated business decision to avoid reporting suspicious orders. McKesson-Aurora's failure to report suspicious orders to the DEA is particularly egregious for two reasons.

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[4] We are also aware of another drug-trafficking organization — totally separate from the Steinke DTO discussed above — that was based in and around Alamosa, Colorado. This DTO was operating in 2012. We have uncovered evidence to show that many persons associated with this DTO filled prescriptions at Lajara Pharmaceutical Center, which partly accounts for that rural pharmacy's unusually large orders. Again, McKesson-Aurora did not alert the DEA about any suspicious orders placed by the Lajara Pharmaceutical Center, even after the media broke the story on October 11, 2012, that the individuals associated with the DTO had been arrested and charged.

[5] The United States Attorney's Office for the District of Colorado is not the only such office currently investigating McKesson's conduct. This civil penalty is, of course, separate and apart from any other civil penalties that could be pursued by other U.S. Attorneys across the country, all of whom may bring separate cases against McKesson. All of these cases are also separate and apart from administrative actions that could be brought directly by the Drug Enforcement Administration to revoke or suspend McKesson-Aurora's DEA Certificate of Registration and the Certificates of Registrations of McKesson's other distribution centers.

First, what the law mandates of distributors like McKesson-Aurora is minimal and easily accomplished. Unlike some regulatory regimes in which the government forces companies to submit to some time-consuming, burdensome, and cost-prohibitive enforcement process, what the DEA asks its registrants to do with respect to suspicious orders is quite simple: design a system that identifies suspicious orders and report any suspicious orders to the DEA. And yet, for several years, McKesson-Aurora never bothered to report to the DEA what were clearly suspicious orders.

Second, McKesson-Aurora — of all DEA registrants — should have known better. McKesson paid $13,250,000 and entered into the 2008 Settlement Agreement and the MOA with the United States for its failure to report earlier suspicious orders by pharmacies. McKesson then designed a compliance system, the CSMP, to make it even clearer and easier to obey this simple reporting requirement. McKesson-Aurora, however, then immediately set its mind to disabling this system. An illustrative and predictable result was that McKesson-Aurora went on to sell tens of thousands of dosage units of oxycodone and hydrocodone to a pharmacy run by the same man McKesson-Aurora had just been punished for failing to monitor. Also predictably, that same man proceeded to run a drug-trafficking organization out of his pharmacy, and people were killed by the narcotics that his drug-trafficking organization dispensed.

Before we pursue litigation, I am willing to meet with you to discuss the allegations outlined in this letter. I am willing to provide you with the opportunity to present facts that may be relevant to the resolution of this matter. I am also open to discussing settlement prior to initiating a civil action in federal district court. If you are interested in discussing this matter, please contact me at your earliest convenience, but no later than August 26, 2014. I can be reached at (303) 454-0109. I look forward to hearing from you.

Sincerely,

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